

Counterfeiting of HIV/AIDS Medicines: Implications for Global Epidemic - Recommendations for Workplace Programs

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Declaration

I, the undersigned, hereby declare that the work contained in this assignment is my own original work, and that I have not previously in its entirety or in part submitted it to any university for a degree.

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Summary

During recent past years the counterfeiting of medicines has increased globally at an alarming rate, particularly in the developing world. Numerous patients have become casualties. Importantly, medicines used for the treatment of people with Acquired Immune Deficiency Syndrome (AIDS) and its associated maladies have not escaped the attention and interest of criminals where multiple therapeutic categories of medicines have been increasingly targeted for counterfeiting.

According to Van Niekerk [Van Niekerk, Anton. (2001). Moral and social complexities of AIDS in Africa. University of Stellenbosch], **“it is commonplace to identify and bewail a plethora of problems in the developing world generally, and in Africa in particular. Poverty, illiteracy, famine, political instability, natural disasters, and many more misfortunes dominate the history of this part of the world over the past 50 years. It was therefore adding uncalled (undeserved?) insult to already overwhelming injury when HIV/AIDS visibly struck the world since mid-1980. In spite of all the other calamities that Africa has to deal with, it nevertheless is no exaggeration to claim that HIV/AIDS nowadays constitutes the most serious health and social crisis and challenge that has ever befallen the continent”**. Similar patterns involving HIV/AIDS are now emerging on other continents.

One objective of this recent research study was to explore possible relationships between the growing scourges of the worldwide counterfeiting of medicines and parallels with the expanding global HIV/AIDS pandemic - as well as to examine potential relationships and risks associated with other diseases that have been observed to have ‘special associations’ with HIV and AIDS [e.g. sexually transmitted infections (STI’s), Tuberculosis (TB) and Malaria] - and possible impact on the “World of Work”. A second and important objective was to develop Recommendations for Workplace Programs. The information gathered has also been used to propose future studies regarding HIV/AIDS and counterfeiting.

In the developing world, antibiotics and anti-parasitic medicines are included among the counterfeiters' favorite targets. Strong parallels exist between locations where counterfeiting of medicines is taking place/product being distributed/sold and where HIV/AIDS is most prevalent and/or where the epidemic is expanding progressively. Counterfeiting of medicines used for treating HIV/AIDS raises the possibility of additional future complications developing in managing other global diseases such as Malaria and Tuberculosis, not to mention exacerbating the potential for developing resistance and encouraging mutation of the HI virus itself. It is also noteworthy that certain medical devices have also been found to be counterfeit.

Global demographics and with particular reference to projected growth rates of populations of the developing world are of specific relevance to this subject of anti-counterfeiting and medicines used for the treatment of HIV and AIDS. Indeed, next generations of humanity appear to be at unnecessary risk of being caught up in a confluence of forces whereby the practice of the counterfeiting of medicines could result in significant complications and unforeseen consequences regarding management of the global HIV/AIDS crisis. Following the research, recommendations for workplace programs were developed. The research study concludes with a comprehensive set of references.

Opsomming

Die problematiek aangaande die vervalsing (namaak) van medisyne word nou wereldwyd ervaar en het 'n impak op beide die geïndustrialiseerde en die ontwikkelende wereld. Menige medisyne in terapeutiese kategorieë is tot op hede as vervals geïdentifiseer, met die direkte resultaat dat hulle 'n minemale of geen terapeutiese uitwerking het nie. Wat nog erger is, is dat hierdie middels uiters gevaarlik is om te gebruik en selfs lewensgevaarlik kan wees. Dit is van groot betekenis dat ook medisyne wat bestem is om persone met HIV/VIGS te behandel, as vervals aangetoon is – en soedoende tot nog toe onbekende gevolge vir pasiënte, die werkomgewing en ongekende risiko's vir wereldwye gesondheidsorg en internasionale veiligheid en sekuriteit inhou. In hierdie studie word die onderwerp in taamlike besonderhede bestudeer en daar word afgesluit met aanbevelings oor programme in die werkplek wat ontwerp is om sorg en ondersteuning te bied aan werkers met HIV/VIGS. Verdere studie word ook aanbeveel om die tregende probleme wat volg op die vervalsing van medisyne in die behandeling van persone met HIV/VIGS, en die implikasies hiervan, die hoof te bide.

1. Introduction

During recent past years the counterfeiting (faking) of medicines has increased globally at an alarming rate. The lion's share of the available counterfeit medicines has been in the developing world [McGregor, A. Counterfeit drugs flood developing world. *Lancet* 350, 1960 (1997)], however, there have also been some notable examples in industrialized nations, for example the United States of America [Counterfeit drugs a health threat in US (Editorial). *Scrip World Pharmaceutical News*, No. 2662 (2001)]. Numerous patients in these and other geographic locations have been the primary casualties following the consumption of the counterfeited medicines, which are said to account for up to ten percent [Jahnke, W.O. (2004). Counterfeit Medicines and the GPHF-Minilab for Rapid Drug Quality Verification. *Phrm. Ind.* 66, No. 10, 1187-1193] of the global pharmaceutical market (estimated global value of counterfeits could be as high as billions of US\$ equivalent). Importantly, medicines used for the treatment of patients that experience Acquired Immune Deficiency Syndrome (AIDS) and its associated maladies - which is universally believed to be caused by infection with the Human Immunodeficiency Virus (HIV) - have not escaped the attention and interest of counterfeiters. As a result, multiple therapeutic categories of medicines used in the treatment of these patients impacted by HIV/AIDS have been increasingly targeted for counterfeiting [Goodman. P.S. (2002) China's Killer Headache: Fake Pharmaceuticals. *The Washington Post Foreign Service*. These include medicines aimed at either destroying the HI virus (highly active anti-retroviral therapy [HAART]), medicines used for preventing secondary and opportunistic infections (e.g. antimicrobial agents) commonly associated with HIV/AIDS in particular, as well as 'other' medicines (for example anti-wasting medications, immune system boosters, nutritional supplements including vitamins etc).

According to van Niekerk (Director of Center for Applied Ethics of Stellenbosch University), "It is commonplace to identify and bewail a plethora of problems in the developing world generally, and in Africa in particular. Poverty, illiteracy, famine, political instability, natural disasters, and many more misfortunes dominate the history of

this part of the world over the past 50 years. It was therefore adding uncalled (undeserved?) insult to already overwhelming injury when HIV/AIDS visibly struck the (also developing) world since mid-1980. In spite of all the other calamities that Africa has to deal with, it nevertheless is no exaggeration to claim that HIV/AIDS nowadays constitutes the most serious health and social crisis and challenge that has ever befallen the continent". This having been said, similar patterns involving HIV/AIDS are now emerging on other continents encompassing large sections of the developing world. Included here is south Asia (notably India and Pakistan), Greater China, and parts of south East Asia (Thailand), Indo-China (e.g. Myanmar, Laos, and Vietnam) and Eastern Europe including Russia, as well as Latin America, among others - where the HIV/AIDS pandemic has been expanding rapidly at differing rates.

Given the business attractiveness and associated significant profitability of the global pharmaceutical markets (2003 market value was in excess of US\$ two hundred billion) and its constituent products, together with the lack of appropriate laws and effective law enforcement in numerous countries, it is therefore no surprise that during recent years the counterfeiting (faking) of medicines internationally has continued to increase rapidly. This counterfeiting is being increasingly documented, and is being said to be perpetrated by criminals. Purveyors of crimes involving counterfeiting typically includes mafias, triads, gangs and other criminals and in this context, predators on the sick and needy. Numerous patients in these named geographies and others to where the fake medicines have been exported or marketed have been the primary casualties [Africa News Service, Inc. (2002). South Africa: Health Talks Should Look At False Drugs] following on the consumption of faked and counterfeited medicines. Hundreds of thousands of innocent human beings who have no personal responsibility or accountability for the counterfeiting will as a direct result certainly either lose their lives or become needlessly ill now and increasingly as time moves ahead. [It is important that counterfeiting of medicines (faking – see definition) is not confused with the legal manufacture of generic medicines - once the patent of the original active component/process has expired. To the contrary, quality generic medicines play an important role in global healthcare management. Those generics that meet appropriate GMP standards and that have been

formally approved by healthcare agencies and regulatory bodies are said to be validated as being efficacious in terms of bioequivalence – and are in almost all instances immensely more affordable than the innovative patented medicine].

It is stressed at this point that AIDS, as the acronym implies, is a syndrome and not a disease in its own right. Most patients that eventually succumb to AIDS do so once the body has collectively reached a stage when viral loads are at a high peak, the immune system has been severely compromised, and the patient has been impacted by one or more opportunistic infection or condition. Some are named below by way of example:

HIV/AIDS-related conditions/infections in the adult (examples): Cytomegalovirus infection, Candida albicans (thrush), oral hairy leukoplakia, Kaposi's sarcoma, bacterial periodontal conditions, Herpes simplex, diarrhea, Mycobacterium avium complex, tumors, neurological disease, tuberculosis, Salmonella (non-typhoid) bacteremia, Toxoplasmosis encephalitis, Cryptococcus meningitis, bacterial sinusitis, seizures, HIV-related lymphoma, Pneumococcal pneumonia, Pneumocystic pneumonia, Herpes zoster, Cryptosporidium infection, fungal skin infections, folliculitis, ulceration and pelvic inflammatory disease, among many others.

HIV/AIDS-related conditions/infections in the child (examples): Otitis media, Toxoplasmosis, Meningitis, Lymphoid interstitial pneumonitis, Chicken pox (Herpes zoster) ... among many of the conditions evident in adults as named above.

Medicines prescribed for treating directly this vast spectrum of conditions associated with HIV infection and AIDS fall into numerous therapeutic categories.

2. Research problem and objectives

One objective of this descriptive research study was to explore using currently available information and knowledge possible relationships between the growing scourges of the worldwide counterfeiting of medicines and parallels with the expanding global

HIV/AIDS pandemic - as well as with certain other global diseases. Special reference was paid during research to the developing world - as well as implications for the World of Work. It is of particular significance that workplace HIV/AIDS treatment and support programs are being increasingly implemented as part of a holistic approach to managing HIV/AIDS in the context of the World of Work and as a component of overall risk management. Another objective was to develop recommendations for workplace programs.

The information gathered has been used to explain modern-day occurrences and trends related to counterfeiting of medicines, as well as to propose future studies that would aim to more specifically identify the extent of medicines used in the treatment of HIV/AIDS that are being counterfeited; examining potential relationships and risks associated with other diseases that have 'special associations' with HIV and AIDS (these include various sexually transmitted infections (STI's), Tuberculosis (TB) and Malaria;) and possible impact on the World of Work. Recommendations for workplace programs have been developed.

The research study proposed that the most unfortunate and inhuman, immoral and unethical practice of the counterfeiting of certain medicines used in the overall healthcare management of patients with HIV/AIDS is placing unnecessary risks to and burdens on such people as well as on overall healthcare management and will over time it is believed also place additional and unnecessary burdens on the World of Work. The practice of counterfeiting medicines is potentially seriously compromising patient care, and has the added potential for exacerbating the current global HIV/AIDS pandemic – this poses a special strategic risk to specific population groups particularly in the developing world and in the World of Work. It also raises the possibility of additional future complications developing in managing other important global diseases such as Malaria and Tuberculosis, not to mention exacerbating the potential for developing resistance and encouraging mutation of the HI virus itself as the direct result of treatment regimens being interrupted or severely compromised through consumption of (inefficacious and sub-standard) counterfeited medicines.

3. Literature study

3.1 Definition of concepts

Counterfeited medicines include medicine that has been deliberately and fraudulently mislabeled in terms of identity or source. They include products with the correct ingredients or the wrong ingredients, without active ingredients or with fake packaging. They can also include a genuine product that has expired and has then been fraudulently relabeled. [WHO Department of Essential Drugs and Other Medicines. Guidelines for the development of measures to combat counterfeit drugs WHO/EDM/QSM/99.1. WHO. Geneva (1999)].

The developing world implies nations that are not yet industrialized

4. Research methodology

Methods used for gathering information included detailed desk research of contemporary global available information on the subject of counterfeiting (faking) of medicines. This included an extensive literature search, fieldwork study and direct observation, participation in person-to-person and group meetings/interviews, internet reviews of the World Wide Web, meetings and discussions with researchers/authors/writers, as well as the active participation in international intellectual property and scientific symposia and conferences on subjects related to counterfeiting of medicines.

5. Results

The results of this research comprise the interpretation of the gathered information related to the prevalence of the counterfeiting of medicines intended for the treatment of people with HIV/AIDS, notably in the developing world. Strong parallels exist between

locations where counterfeiting of medicines is taking place (or to where these medicines are being distributed) and where HIV/AIDS is most prevalent and/or where the epidemic is expanding progressively. (While this is not seen as a direct cause-and-effect relationship at this point, this research draws attention to the fact that the rampant counterfeiting of medicines that is taking place in many parts of the developing world poses massive and unprecedented threats to management of the global HIV/AIDS pandemic. It also has the potential to undermine efforts to bring the pandemic under control and poses possible new threats to global health, safety and security).

In determining which medicines are most frequently counterfeited in both industrialized and developing countries, references have been made to many classes of drugs. Contrary to what one might expect, it is not necessarily the most expensive drugs that are most often counterfeited. In the developing world, antibiotics and antiparasitics are the counterfeiters' favorites. Medicines used for treating HIV/AIDS that have to date been found to be counterfeited include biologic products e.g. growth hormones used in treating HIV/AIDS wasting, highly-active anti-retroviral drugs, antibiotics, anti-parasitic medicines, anti-cancer therapies, and nutritional supplements e.g. complex multi-vitamins.

Examples of specific products used in the treatment of HIV and AIDS and associated conditions that are documented as having been counterfeited/implicated in counterfeiting cases to date include:

5.1 Medicines aimed at destroying the HI virus (highly active anti-retroviral therapy [HAART])

- Combivir/3TC ® – (zidovudine + lamivudine) a combination highly-active antiretroviral (Nucleoside Reverse Transcriptase Inhibitor analogue) frequently used for the treating patients with HIV and AIDS.
- Ziagen ® (abacavir sulfate) – a synthetic carbocyclic nucleoside analogue that has inhibitory activity against HIV.

- AZT – Also known as the brand name Retrovir ® this is also sometimes referred to as an AIDS-defining drug

5.2 Medicines used for preventing secondary and opportunistic infections (e.g. antimicrobial agents) commonly associated with HIV/AIDS

- Cotrimoxazole – a broad spectrum antibiotic (trimethoprim sulfamethaxazole) used for treating infections frequently associated with AIDS complications e.g. bronchitis
- Benzetacil ® ((Penicillin G) – the original antibiotic used for treating various complications associated with AIDS, as well as sexually transmitted infections (AST's)
- Mefloquine – an anti-malarial product used in the treatment of Malaria particularly in the developing world
- Artesunate – a leading anti-malarial commonly used in Southeast Asia in areas where HIV/AIDS is spreading rapidly. The special association between the HI virus and Malaria needs to be borne in mind
- Ampicillin – a semi-synthetic penicillin commonly used to combat secondary upper-respiratory infections and other penicillin-sensitive bacterial infections
- Canesten-V ® - (cotrimazole) an anti-fungal preparation often used for treating yeast infections sometimes associated with AIDS
- Gentamycin sulfate – an antibiotic that is particularly effective against Gram-negative microorganisms frequently found in patients with severely immuno-compromised systems as a result of AIDS as well as in people with cancers. Also used in serious respiratory infections with virulent encapsulated bacteria such as *Streptococcus pneumoniae* and *Haemophilis influenzae* often associated with AIDS

5.3 Other medicines (for example anti-wasting medications, biologicals, immune

system boosters, nutritional supplements including vitamins etc).

- Epogen ® – stimulates the production of red blood cells and is intended for use in cases of severe anemia and is used in patients with kidney failure on dialysis. Also used in HIV/AIDS patients experiencing complications as the result of treatment anti-retrovirals
- Procrit ® – (Epoetin alfa) – as above
- Neupogen ® (Filgrastin) – a human granulocyte colony stimulating factor which helps the bone marrow produce neutrophils (white blood cells) used for fighting infection. It is intended to decrease the incidence of infection particularly in immuno-compromised patients including people with AIDS
- Serostim ® – An approved treatment for people with wasting syndromes and opportunistic infections commonly experienced by people with HIV/AIDS. This drug mimics the human growth hormone and helps the body maintain and build bone, muscle and organ tissue
- Centrum ® – a premium, complex multi-vitamin/mineral/anti-oxidant preparation that is used as supportive therapy in immuno-compromised patients with HIV/AIDS
- Nutropin ® – (Somatropin) a growth hormone used in cases of growth deficiency including in patients with advanced AIDS
- Gammaguard ® – a medicine used to boost the immune system
- Ranitidine – used to regulate the amount of acid produced by the stomach and taken by patients suffering from heartburn, indigestion and sour stomach – frequent discomforts of patients with AIDS

The incidence of counterfeited medicines on the market varies from country to country worldwide with a significantly and disproportionate incidence (60%) being observed in the developing world than is the case in industrialized nations (40%). At the current time a general estimate of the prevalence of counterfeited medicines is around five % to ten % is frequently cited. In some more extreme examples instances of as high as 50% and

higher for certain products have been reported. Counterfeit medicines have been found at almost all points of the distribution chain right down to retail pharmacies and hospital dispensaries. While many countries of the world have been impacted it needs to be noted that Africa experiences a disproportionately high incidence of counterfeited medicines in certain countries. South Africa has not escaped the scourge of counterfeiting and while definitive information about the actual incidence is not readily verifiable, it has been reported that percentages of counterfeited medicines circulating within the market may run at up to 10 percent. This includes fake and expired and expired medicines. It is significant that in Africa as a whole, between 25% and 50% of the market is counterfeit [International Federation of Pharmaceutical Manufacturers Association (IFPMA)].

It is also noteworthy that over and above medicines used for the treatment of patients with HIV/AIDS, medical devices have also been found to be counterfeit. These include condoms and diagnostic test kits used for diagnosing the HIV status of individuals. Laboratory analysis has found that the said test kits did not produce accurate results. This means that people who were HIV-positive might have been reported as HIV-negative and vice versa- and devices used for protection against transmission of the HI virus may be ineffective. This could have particular significance for workplace programs.

6. Demographics and the developing world

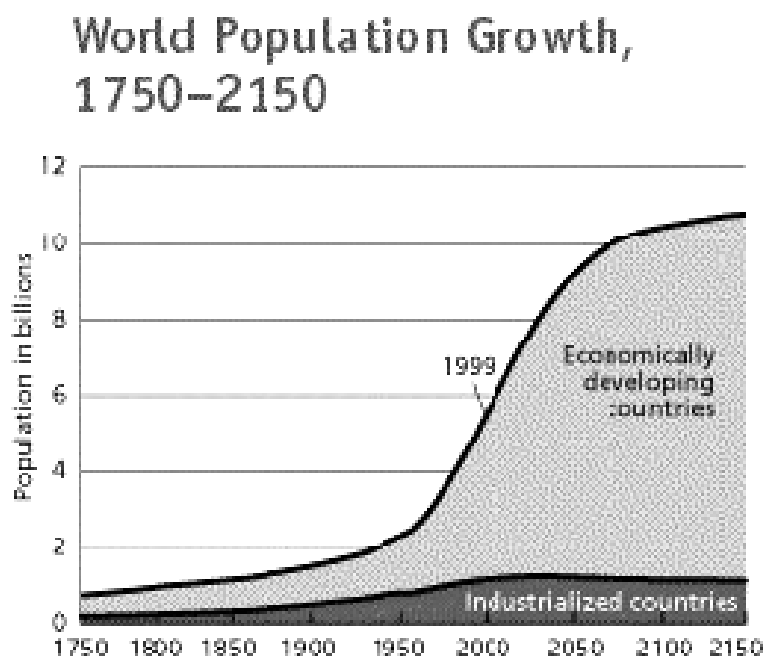
Global demographics and with particular reference to projected growth rates of populations of the developing world are of specific relevance to this subject. Current demographic surveys of the industrialized world indicate a population of around less than two billion people at this time AD 2005 with no significant increases being projected towards AD 2150. These provides sharp contrast with the scenario projected for the developing world with an estimated steady growth being anticipated towards the year AD 2050 when the current population of over four billion people is predicted to have increased to over eight billion populous by year AD 2150. Once again, attention is drawn to the significant growth in the counterfeiting of medicines in the developing world

where the global population is also growing most rapidly. Additionally, HIV/AIDS is currently spreading exponentially in many parts of the developing world.

6.1 World population metrics

According to currently available information and projections, while the world population will keep growing, growth in industrialized nations is projected to be small. Most of the growth in populations will take place in the developing world countries [*Population Connection*].

6.2 Graph - Consolidated population growths



Source: *Population Connection*

6.3 Correlation between epidemiology of HIV/AIDS and global demographics with reference to counterfeiting of medicines

As at January 24, 2005 the world's population has been projected at 6, 4 billion people (<http://www.census.gov/cgi-bin/ipc/popclockw>). By the year 2050 the world's population is projected to be in excess of nine billion persons (U.S. Bureau of the Census, International Data Base. <http://www.census.gov/ipc/www.worldpop.html>) almost all of this growth is estimated as taking place in the developing world.

According to the U.S. Census Bureau, it has been clear for a number of years that mortality estimates and projections for many countries would have to be revised due to AIDS mortality, the lack of accurate empirical data on AIDS deaths, the paucity of data on HIV infection among the general population, and the absence of tools to project the impact of AIDS epidemics into the future have all hampered these efforts. Currently, although the accuracy of data on AIDS deaths has not substantially improved, knowledge of HIV infection has expanded and modeling tools have become available to project current epidemics into the future [U.S. Census Bureau. (2002). Global Population Profile].

Importantly, no projections of note take into account the incidence and growing threat of counterfeiting of medicines in arriving at HIVC/AIDS projections and estimates/impact studies. Hence the recommendation follows that this area needs to be comprehensively researched so as to attempt to quantify the future risks associated with counterfeiting of medicines particularly insofar as HIV/AIDS and the global epidemic are concerned.

7. Implications of counterfeiting of medicines

7.1 HIV/AIDS: It is of particular relevance that counterfeiting of medicines is currently increasing most significantly in regions where HIV infection and AID syndrome has been/is also generally expanding most rapidly. Of additional significance is the fact that

counterfeiting has been expanding in incidence (or has been impacting) most significantly in geographies that comprise the developing world. The quality of pharmaceuticals has become more and more a global concern and the lack of reliable quality assurance systems in many developing countries often contributes to the devastation of diseases, for example HIV/AIDS, TB and Malaria (German Pharma Health Fund (GPHF) <http://www.gphf.org>).

The counterfeiting of medicines, including those intended for treating patients with HIV/AIDS, needs to be of concern to governments and healthcare organizations across the globe and urgent and coordinated steps need to be implemented to address this. Importantly, the potential impact that this might have on the expanding global pandemic of HIV/AIDS needs to be of even graver concern to all those constituencies involved in the fight against HIV and AIDS worldwide. This should be a given among responsible citizens irrespective of which constituency they represent.

However, and in particular, the implications for HIV/AIDS, given the marked prevalence of counterfeiting of medicines which are currently found being manufactured and distributed in the developing world, the fact that the lion's share of populations with HIV and AIDS are currently found in the developing world, the fact that HIV/AIDS is expanding exponentially in the developing world, and the reality that the future projected growth of the world's population is anticipated to come from the developing world - next generations are at profound risk of resulting in a confluence of forces whereby the current practice of the counterfeiting of medicines could result in hitherto massive complications and unforeseen consequences regarding management of the global HIV/AIDS crisis. The potential problems include issues such as treatment failure, development of drug-resistance and mutation of microbes including the HI virus itself [Ten Ham, M. (1992) Counterfeit drugs: implications for health. *Adverse Drug Reactions. Toxicol. Rev.* 11, 59]

Also of significance is that workplace programs that are increasingly being put in place as part of adopting a holistic approach to HIV/AIDS and risk management in the World of

Work could very well be placed in jeopardy as a direct result of the counterfeiting of medicines.

Finally and also of collateral significance, the prevalence of counterfeited diagnostic test kits that have been documented as having produced inaccurate results raise the alarm that some patients might have been diagnosed HIV-negative when they were positive, and others HIV-positive when they were in fact 'negative'. This raises significant additional ethical and moral issues and again highlights the serious international problems, risks and threats associated with counterfeiting of health care assets. In this connection, the realities of practices of dehumanization, discrimination, victimization, ostracization and immiseration of persons (victims and survivors) of those impacted by HIV/AIDS – particularly those unwittingly and unfairly, unethically and immorally impacted by counterfeiting, need to be considered.

7.2 Sexually Transmitted Infections (STI's): Sexually transmitted infections encompass a wide range of afflictions transmitted commonly through intercourse. These comprise a variety of microbial species. Patients infected with STI's are particularly susceptible to infection with the HI virus – it is said that persons infected with an STI are four times more susceptible to infection with the HI virus. There are various reasons for this. Implications included here for consideration are that in high-risk areas and among high-risk groups, the consumption of counterfeited medicines by patients being treated for 'common' STI's will be at additional risk of being infected by HIV – and will in likelihood further fuel the spread of HIV worldwide, particularly among sexually-active groups.

7.3 Malaria: Malaria and HIV/AIDS are said to enjoy a 'special relationship' with each other. Both the Malaria parasite and the human immunodeficiency virus thrive in bodies that are immuno-compromised. Patients suffering from Malaria are also particularly susceptible to infection with the HIV and vice versa. Implications include the fact that HIV and Malaria are currently spreading rapidly in the developing world, notably in the geographies of Indo-China. The availability of counterfeited medicines is already

documented in these areas as being widespread, particularly drugs aimed at treating Malaria e.g. artesunate [Newton, P. et al. (2001). Fake artesunate in Southeast Asia. THE LANCET]. Thus the spread of HIV and AIDS could potentially accelerate in these geographies.

7.4 Tuberculosis: Infection with *Mycobacterium tuberculosis* which often results in Tuberculosis (TB) is commonly associated with circumstances where there is poverty, malnutrition and close living conditions, among other circumstances. Tuberculosis is a disease long associated with less favorable socio-economic conditions. Similarly and as with the case of the human immuno deficiency virus, the TB bacillus thrives furiously in bodies that are immuno-compromised – notably HIV-positive persons. People with TB are notably susceptible to infection with the HIV and vice versa. Special implications here include the fact that both HIV/AIDS and TB are spreading rapidly in some parts of the world, notably among developing countries that have a lower socio-economic status. The issues associated with counterfeited medicines being consumed by patients are numerous and the accelerated spread of TB and HIV/AIDS could be an end result.

It is of relevance that the Global Fund as well as numerous international philanthropic organizations (e.g. Presidents [US] Emergency Plans for AIDS relief) have placed a particular focus of attention on the subjects of Malaria, HIV/AIDS as well as on Tuberculosis. The practice of counterfeiting of medicines has the potential to undermine these initiatives and efforts as time progresses.

7.5 General - Counterfeiting of medicines used in treating patients with HIV/AIDS:

Results of the descriptive research study indicate that a wide range of medicines used in treating patients with HIV/AIDS have to date been counterfeited. This research does not include counterfeiting of condoms used in prevention programs for HIV and AIDS, and HIV diagnostic kits/reagents routinely utilized in voluntary testing and counseling programs in the World of Work.

In the developing world the countries most frequently associated with the practice of counterfeiting of medicines include Greater China, Russia and other east European countries, various Latin American states and a significant array of countries located in Southeast Asia, Indo China and south Asia, notably India and Pakistan.

The prevalence of counterfeited medicines used for treating HIV/AIDS significantly increases risks to mankind particularly in the developing world and is highly likely to complicate the management of, and fuel the spread, of HIV and AIDS globally.

8. Conclusion and recommendations

Considering all of the above and previous findings related to counterfeiting of medicines, there are strong indications and credible evidence that medicines used in the treatment and management of HIV/AIDS are being counterfeited internationally. This will increasingly become a critical universal healthcare issue requiring effective resolution. According to Suzuki (WHO Executive Director in charge of Health Technology and Pharmaceuticals) “No country is immune from the threat of counterfeit drugs but those with weakly regulated pharmaceutical markets are suffering most”.

Over and above general recommendations related to resolving this problem viz. a) that significant additional scientific research be conducted in the area of counterfeiting of medicines; b) that there be increased responsible fact-based education by relevant stakeholders of publics about counterfeiting of medicines and how to avoid unnecessary risks associated with these; c) that all governments worldwide place necessary and appropriate legislation in situ aimed to discourage the practice of counterfeiting of medicines; d) that this legislation be effectively enforced and that appropriate counterfeit-discouraging censures are issued to perpetrators of crimes related to counterfeiting of medicines – **that importantly and particularly, workplace programs (designed to holistically assist and treat patients with HIV/AIDS using medication) implement the following practical principles and practices with regards to the use of medicines:**

- 1) Exercise due caution regarding the purchase of medicines for workplace programs. Product should be received in original (not broken bulk or re-packaged) packaging. Medicines should only be sourced from 'pre-qualified' sources.
- 2) The source of the medications needs to be carefully validated during purchasing routines. Where possible, purchase should take place as close as possible in the supply chain to the primary original manufacture. Alternatively, from well trusted approved and credible wholesalers, or from distributors that are positioned close to source, -and that are both traceable and verifiable. Relevant supporting documentation should be requested and carefully inspected on a batch-by-batch basis.
- 3) Supply chain sources of medicine need to be inspected/audited periodically, the objective being to ensure that reliable and authentic manufacturers/distributors are being used to supply relevant medicines.
- 4) Prudence needs to be exercised when accepting deeply discounted prices in the purchase of medicine. Where unusually low prices are offered the reasons for this need to be explored and fully understood by the purchaser. The principle of *caveat emptor* should be noted. The purchase of medicine from unauthenticated suppliers should be avoided.
- 5) When purchasing stock comprising multiple batches and/or expiry dates, particular care should be taken. Ideally, bulk purchases should comprise only one or at least a minimum number of different batches/expiry dates of the medicines.
- 6) Relevant and appropriate authentication and security devices on the packaging should be considered for use where appropriate.
- 7) Quality control checks on each batch of the purchased medicines should be performed wherever possible. These need to be consistent with WHO and other relevant guidelines regarding verification of medicines and specific ingredients. In this connection, product needs to be appropriately sampled and certain testing performed (e.g. using the German

Pharma Health Fund Minilab for Rapid Drug Quality Verification). This would include identification of key active therapeutic components at a minimum. The purchase should be compared with a type-sample received directly from the original manufacturer.

8) Where after careful inspection any concerns regarding the quality of the purchased medicines are evident or any suspicions are raised the Corporate Security and/or Compliance or similar relevant departments of the manufacturer of the (authentic) medicine needs to be contacted and these suspicions/concerns discussed.

9) When counterfeit medicines are detected in the course of purchasing, the source as well as the original manufacturer together with relevant local and national health authorities/drug regulatory agencies should be immediately notified.

10) Industry needs to be obligated to report details of all instances of where medicines manufactured/marketed/distributed/sold by themselves have been found to be counterfeited. These need to be reported to a national authority who in turn should report this to an appropriate global coordinating body/authority.

11) Educational programs need to be put in place within the workplace HIV/AIDS program so that those involved in managing such programs are alert to the possibility of the existence of counterfeited medicines in their stocks. This is of particular importance in the developing world.

12) The issue of counterfeiting of medicines needs 'to come out into the open' in a responsible and orderly fashion. This should be done in a responsible manner that avoids consumer 'panic' but which yet at the same time communicates the reality of the growing scourge to constituencies that share a responsibility of acting appropriately on same on a 'need-to-know' basis.

9. Additional studies recommended

This paper draws attention to the significant threat posed to humanity by the steadily increasing practice of the counterfeiting of medicines, including in both the industrialized and (most notably) the developing world. It also draws attention to the geographic correlation between areas where medicines (importantly those used for treating patients with HIV/AIDS) are most prevalently counterfeited (or where counterfeited medicines are most commonly found) and geographic locations currently being significantly impacted by HIV/AIDS. This applies equally to areas where incidence is notably high, and also locations where HIV/AIDS is now expanding exponentially (e.g. India and China). Thus assessment of the impact that counterfeiting of medicines is having on the global spread of HIV and AIDS is a relatively new field about which there is currently little published research and data. To fully understand this phenomenon and to quantify a realistic risk profile to future populations, human health, and related topics associated with global safety and security it is believed that ongoing research studies are required.

These include:

- Studies designed to identify and where possible quantify which categories of medicines (by therapeutic class and brand/generic) commonly associated with the treatment and management of HIV/AIDS has been/are currently being counterfeited/distributed. Particular emphasis needs to be placed on the developing world.
- Additional studies are required to accurately identify and highlight the specific countries where counterfeited medicines used in the treatment of HIV and AIDS are commonly being manufactured and to where they are being distributed.
- Further studies are required as to how the practice of counterfeiting of medicines can be effectively addressed. This will include identifying and exposing countries where the counterfeiting is known to have taken place; countries that do not have

effective laws in place to deter the practice of counterfeiting of medicines or the distribution thereof; and countries that may have laws in place but do not enforce them appropriately.

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